UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 01-1343 (JR)
	:	
FOOD AND DRUG ADMINISTRATION, *et al.*,	:	
	:	
Defendants,	:	
	:	
and	:	
	:	
GENEVA PHARMACEUTICALS, INC.,	:	
	:	
Intervenor,	:	
	:	
and	:	
	:	
TEVA PHARMACEUTICALS U.S.A., INC.,	:	
	:	
Intervenor.	:	

MEMORANDUM ORDER

Merck & Co. holds the U.S. patent on the highly successful anti-cholesterol drug lovastatin, which Merck markets as Mevacor®. The patent was to expire on June 15, 2001. On that date, at least two manufacturers of generic equivalents[1] were waiting for approval of their applications to market generic versions of Mevacor. On the same date, Merck was waiting for FDA approval of its application for a six-month extension of its

[1] TEVA Pharmaceuticals U.S.A., Inc. and Geneva Pharmaceuticals, Inc., both of which have intervened in this action.

patent rights, pursuant to the Food and Drug Administration Modernization Act of 1997 (FDAMA), codified in part at 21 U.S.C. § 355a, after its earlier submission of a FDA-requested study of the effect of lovastatin on children. At 4:18 p.m. EST on June 15, 2001, FDA's Division of Metabolic and Endocrine Drug Products faxed to Merck a memorandum from the Pediatric Exclusivity Board denying Merck's application for pediatric exclusivity. That same day[2] FDA approved five abbreviated new drug applications (ANDAs) for generic equivalents of Mevacor. Merck immediately brought this action, asserting that FDA's denial of "pediatric exclusivity" was arbitrary, capricious, or otherwise not in accordance with law, in violation of the Administrative Procedure Act.

I granted Merck's application for a temporary restraining order on June 16, 2001 – staying the effectiveness both of FDA's refusal to grant six-month exclusivity under FDAMA and of the ANDA approvals – and set Merck's application for preliminary injunction down for hearing at 4 p.m. on June 19, 2001. After that hearing, and for the reasons set forth in this memorandum, I have decided to extend the temporary restraining order for an additional ten days pursuant to Fed. R. Civ. P.

[2] According to the representations of counsel at a hearing on Merck's application for a temporary restraining order held on Saturday, June 16, 2001.

65(b), to order the trial of the merits of this action to be advanced and consolidated with the hearing of Merck's application for a preliminary injunction pursuant to Fed. R. Civ. P. 65(a), and to set the matter down for trial on July 3, 2001, at 9:30 a.m.

BACKGROUND

FDAMA, enacted in 1997, provides a six month extension of the statutory market exclusivity given to a new drug if, upon FDA's request, the manufacturer studies the effect of the drug on children. In order to qualify for this "pediatric exclusivity" period, drug manufacturers must comply with either 21 U.S.C. § 355a(d)(2) or (d)(3), which are the applicable statutory standards.

On May 20, 1998, FDA included lovastatin as a priority drug on the Pediatric List. Merck submitted a proposed written request for pediatric studies to FDA on August 13, 1998. After staff discussions, on February 3, 1999, FDA issued a formal written request pursuant to 21 U.S.C. § 355a(d)(1) for information on a study of lovastatin in adolescent males (which Merck had already completed) and on a study supplementing the existing data on adolescent males with information on the use of lovastatin in adolescent girls aged 10-17. The written request contained no specification of how many girls should be treated,

what the duration of treatment should be, or what the duration of the study should be. Merck responded with a proposed "written agreement" that would have provided further details of the proposed study,[3] but FDA declined to enter into a written agreement.

On May 18, 1999, the FDA amended its written request to specify a desired trial period of six months instead of the three month period detailed in Merck's written proposal. As amended, the written request asked for a "placebo-controlled trial in adolescent girls of a minimum six months' duration." Merck then formally submitted to FDA the protocol for its proposed study, showing, among other things, that the study duration would be 28 weeks, including a four week placebo "run in" period, and that the duration of treatment on lovastatin would be 24 weeks, with a seven day period of leeway (earlier or later) to accommodate the scheduling needs of study participants. FDA did not inform Merck that this study design would be inadequate to meet the six month duration requirement of the amended written request.

[3] See 21 U.S.C. § 355a(d)(2). Written agreements are rare. In a recent report to Congress, FDA has taken the position that, because of the level of detail required, written agreements make it less likely that applications for pediatric exclusivity will be granted. Food and Drug Administration, The Pediatric Exclusivity Provision – January 2001 Status Report to Congress, at 7 (2001). See http://www.fda.gov/cder/pediatric/reportcong01.pdf (visited June 20, 2001).

Merck submitted its pediatric study reports to FDA on April 18, 2001. FDA had ninety days, or until July 17, 2001, in which to evaluate these reports, 21 U.S.C. § 355a(e), but it acted in less than sixty days. The June 15, 2001 memorandum of the Pediatric Exclusivity Board (which for purposes of this proceeding will be assumed to have been final agency action) stated the following reason for its conclusion:

> [O]nly 5 girls were treated with lovastatin for 6 months or more. A study in which only 5 girls were treated for 6 months or more could well miss potential safety issued associated with long-term exposure, if any. Therefore, the Board concluded that Merck failed to meet this term of the WR and pediatric exclusivity is denied. (Emphasis added.)

ANALYSIS

What Merck challenges is a decision of FDA's "Pediatric Exclusivity Board." I have subject-matter jurisdiction because the determination was final and because there is no means of obtaining further review by the FDA; no party has suggested otherwise. The Board's action is an informal adjudication, reviewable under the "arbitrary, capricious, or otherwise not in accordance with law" rubric of the Administrative Procedure Act.

At this stage of the record's development, it appears that the Board's determination is "not in accordance with law" because it invokes a standard not specified in the statute. A

denial of pediatric exclusivity for failure to meet a single term of a written request would not be in accordance with section 355a(d)(3), which plainly does not require compliance with every single provision of a written request, but requires only that a pediatric study "fairly respond" to a written request.[4] Nor would it be consistent with the statutory standard to deny pediatric exclusivity because of disappointment with data submitted by a manufacturer if the study as a whole is a fair response to the written request.

I have said "it appears" that the Board employed the wrong standard because the Board's memorandum fails to provide an adequate statement of the rationale for its decision. It is not clear from the memorandum whether the Board even considered the study as a whole in evaluating whether Merck had "fairly respond[ed]" to the written request. The Board provided no reasoned explanation of why it ultimately concluded that the length of Merck's study or the number of participants made the study not "fairly respon[sive]," nor did it give any indication that it employed the sort of "care, [] consistency, [and]

[4] The FDA's Guidance for the Industry: Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act, states that "[r]eports of studies that do not completely meet the terms of a Written Request will not qualify [for] an application for pediatric exclusivity." The Guidance, however, is not a regulation. Nor, as FDA acknowledges in the first footnote and again conceded at oral argument in this case on June 19, 2001, does it "create any rights for or on any person [or] operate to bind FDA or the public."

formality" in making its decision that is necessary before this Court – or any court – owes it substantial deference. United States v. Mead Corp., No. 99-1434, Slip Op at 8 (U.S. June 18, 2001) (citing General Elec. Co. v. Gilbert, 429 U.S. 125, 142 (1976); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

"[I]n order to allow for meaningful judicial review, the agency must produce an administrative record that delineates the path by which it reached its decision." Occidental Petroleum Corp. v. SEC, 873 F.2d 325, 338 (D.C. Cir. 1989). In cases where a reviewing court is unable to make a determination because of the agency's failure to explain the grounds for its decision, the proper remedy is a remand for further proceedings. Florida Power & Light v. Lorion, 470 U.S. 729, 744 (1985).

Only an incomplete administrative record has been filed, however, and it is not clear that I have the authority to remand this matter by means of a preliminary injunction before a trial on the merits.

It is accordingly, this ___ day of June, 2001,

ORDERED pursuant to Rule 65(b) of the Federal Rules of Civil Procedure that the temporary restraining order issued on June 16, 2001, is extended for a period of ten days. It is

FURTHER ORDERED that pursuant to Rule 65(a)(2), the trial of the merits of this action will be consolidated with the

hearing on Merck's application for a preliminary injunction. And it is

FURTHER ORDERED that the consolidated trial on the merits is set for July 3, 2001, at 9:30 a.m.

PROVIDED, HOWEVER, that if FDA concedes that the Board employed an improper standard and so notifies the Court, the June 15, 2001 decision of the Pediatric Exclusivity Board will be immediately vacated, and this matter will be remanded to FDA for further proceedings.[5]

_____
JAMES ROBERTSON
United States District Judge

[5] The Court's understanding is that, if the Board's decision is vacated, the provisions of 21 U.S.C. § 355a(e) would operate to extend Mevacor's period of exclusivity of Mevacor until July 17, 2001.

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